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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,328	04/17/2000	ULRICH SPECK	SCH1653	2161

7590 12/31/2001

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HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
1619	

DATE MAILED: 12/31/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/446,328	SPECK ET AL.
	Examiner	Art Unit
	Michael G. Hartley	1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 October 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-45 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 18-45 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

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C ontinued Prosecution Application

The request filed on 10/30/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/446,328 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendment

The amendment filed 10/30/2001 has been entered. New claims 38-45 have been added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-41 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While the specification describes the use of some specific contrast agents it fails to describe the use of contrast agents which are "non-polymer," "non-peptide," "monomeric non-ionic iodine containing" or "dimeric non-ionic iodine containing". There is nothing in the specification to show applicant envisioned these broad, undefined classes of contrast agents, since there is no mention thereof in the specification of such broad classes of contrast agents. The specification fails to show a representative number of contrast agents with these identifying characteristics to show possession of the broad class now claimed. Further, the recitations of "non peptide" and "non-polymer" amount to negative recitations. Any negative limitation must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 187, 196 (CCPA 1977).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Galkin (US 5,844,965).

Galkin discloses methods of mammography using X-ray imaging, wherein the improvement is the use of a contrast agent which is administered prior to mammography. The imaging is obtained on film using X-rays, thus, is clearly projection mammography as claimed, see column 4, lines 44-57.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Galkin (US 5,844,965) or Nitecki (US 5,756,006) in view of Chang (Radiology), Ranney (US 5,260,050), Hilger (US 5,849,259), Brasch (US 6,009,342), Kirpoitin (US 5,411,730) and Platzek (US 6,054,117).

Galkin discloses methods of mammography using X-ray imaging, wherein the improvement is the use of a contrast agent which is administered prior to mammography. The imaging is obtained on film

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using X-rays, thus, is clearly projection mammography as claimed, see column 4, lines 44-57. Galkin teaches that any contrast agent may be employed, as long as it is non-toxic and has some affinity for the cancer tissue.

Nitecki discloses methods of imaging using X-ray imaging (e.g., which is projection imaging onto a film) comprising administering an iodinated contrast agent, see abstract and column 2. Nitecki teaches that the methods may be used for mammography, see column 2, lines 32-35. X-ray mammography is projection mammography, as X-ray imaging projects X-rays through tissue onto film.

Galkin and Nitecki fail to teach all of the contrast agents as set forth in the instant claims or the concentrations thereof. However, the contrast agents recited in the instant claims are known in the art, as shown by Chang, Ranney, Hilger, Brasch, Kirpoitin and Platzek, as well as, applicant's admitted prior art (e.g., the specification states the contrast agents are known).

Chang, Ranney (col. 41, tables 2 and 3), Hilger (example 23b), Brasch (example 2), Kirpoitin (columns 11-12) and Platzek (col. 21) all disclose X-ray contrast agents which are useful for imaging various tissues. The X-ray contrast agents are taught to be equivalent or improved forms of X-ray contrast agents.

It would have been obvious to employ various equivalent or improved X-ray contrast agents in the methods of X-ray (projection) mammography disclosed by Galkin or Nitecki because both teach that various contrast agents may be used, and the prior art generally teaches that various X-ray contrast agents have been used to obtain improved images for various modalities of breast imaging. One of ordinary skill would have been motivated to employ various known X-ray contrast agents to take advantage of their improved properties, such as, decreased side effects, enhanced imaging, etc., as the contrast agents in the methods of Galkin or Nitecki (e.g., which provide a general teaching that X-ray contrast agents are useful in improving mammography). Further, it would have been obvious to one of ordinary skill in the art to optimize the concentrations of the contrast media disclosed in the prior art in the methods disclosed by Galkin or Nitecki. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not

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inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 10/20/2001 have been fully considered but they are not persuasive.

Applicant asserts that Nitecki doesn't teach the low levels of radiation used in projection mammography with contrast agents (e.g., because CT imaging uses high levels of radiation) or that any (all) contrast agents may be used.

This is not found persuasive because the X-ray mammography taught by Nitecki (or Galkin) is not CT mammography (CT/M) as suggested by applicant, rather it is routine X-ray mammography (e.g., or projection mammography) as set forth in the instant claims. The claims are not limited to a particular administered dose of radiation (e.g., low level of radiation), since such a dose is not recited in the claims. The claims only require projection mammography, which is encompassed by X-ray mammography as taught by Nitecki, which projects X-ray through the breast onto film. In response to applicant's argument that Nitecki does not teach that any contrast agent can be used, the prior art clearly provides a teaching that various contrast agents may be used for X-ray imaging of various tissues, including the breasts. Nitecki and Galkin provide a general teaching that X-ray contrast agents are useful for X-ray (projection) mammography, while the other references teach that various improved or at least equivalent X-ray contrast agents may be employed in broad X-ray imaging modalities, which may provide reduced side effects, brighter images, etc. One of ordinary skill in the art would have been motivated to employ the known contrast agents to take advantage of their improved properties in the methods disclosed by Galkin or Nitecki, of mammography using X-ray contrast agents.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where

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this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley
Primary Examiner
Art Unit 1619

MH

December 14, 2001